

**IN THE UNITED STATES DISTRICT COURT  
NORTHERN DISTRICT OF ILLINOIS  
EASTERN DIVISION**

THE MEDICINES COMPANY,	)	
	)	
	)	
Plaintiff,	)	
	)	Case No. 11-cv-1285
v.	)	
	)	
MYLAN INC., MYLAN	)	
PHARMACEUTICALS INC., and	)	
BIONICHE PHARMA USA, LLC,	)	
	)	
Defendants.	)	

**REDACTED MEMORANDUM OPINION AND ORDER**

AMY J. ST. EVE, District Court Judge:

Before the Court is Defendants’ motion to compel testimony and production of information withheld on the basis of privilege by Plaintiff pursuant to Federal Rule of Civil Procedure (“Rule”) 37(a). (R. 184, Mot. to Compel.) Specifically, Defendants seek production of (1) privileged and non-privileged documents and items in Plaintiff’s possession mentioning, discussing, listing, or otherwise relating to Angiomax® Lot No. 1344985; (2) privileged and non-privileged documents mentioning, reflecting, or relating to communications between attorneys or employees of Frommer Lawrence & Haug law firm (“Frommer”) and The Medicine Company (“TMC”) scientist Dr. Rajeshwar Motheram; (3) Dr. Motheram for a follow-up deposition on the subject of TMC’s additional document production as described in this Order; and (4) all documents reflecting payment or non-payment for Lot No. 1344985 and any claim of loss TMC made for the Active Pharmaceutical Ingredient used in making that lot. (*Id.*) On January 17, 2013, the Court granted Defendants’ motion to compel as to all documents

reflecting payment or non-payment for Lot No. 1344985 in addition to any claim of loss TMC made for the active ingredients used in production. (1/17/13 Status Transcript at 7:18.) In addition, the Court granted the requests to re-depose Dr. Motheram regarding the non-privileged aspects of his conversation with Dr. Kuzmich. (*Id.* at 11:5.) At issue here is Defendants’ request to compel production of documents and communications related to Lot No. 1344985, documents related to communications between attorneys and employees at Fromer and Motheram, and the scope of the follow-up deposition of Dr. Motheram.

For the following reasons, the Court grants in part and denies in part the remaining aspects of Defendants’ motion to compel.

## **BACKGROUND**

### **I. Patents-in-Suit**

Plaintiff TMC brought this lawsuit against Defendants Mylan Inc., Mylan Pharmaceuticals Inc., and Bioniche Pharma USA, LLC (collectively, “Mylan”), asserting that Mylan infringed U.S. Patent Nos. 7,582,727 (the “ ‘727 Patent”) and 7,598,343 (the “ ‘343 Patent,” and collectively with the ‘727 Patent, the “patents-in-suit”). The patents-in-suit pertain to pharmaceutical formulations of Bivalirudin and the processes of making Bivalirudin (the “New Process”). (R. 1, Compl.) Bivalirudin is the active ingredient in Angiomax®, an anticoagulant drug used in patients with unstable angina who are undergoing percutaneous transluminal coronary angioplasty. (*Id.* ¶¶ 11, 13.) TMC markets Angiomax®. (*Id.* ¶¶ 11, 13.)

TMC alleges that Mylan, before the expiration of the patents-in-suit, submitted Abbreviated New Drug Application (“ANDA”) No. 202471 to the U.S. Food and Drug Administration (“FDA”), seeking approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of its generic Angiomax® product. TMC avers that Mylan’s

ANDA No. 202471 infringes certain claims of the patents-in-suit.

In response to TMC's lawsuit, Mylan asserted, among others, a defense of inequitable conduct. (R. 185, Memo. Mot. to Compel at 1.) Mylan bases this defense on TMC's alleged deliberate failure to disclose highly material information to the United States Patent & Trademark Office ("PTO") during prosecution of the patents-in-suit. (*Id.*) Specifically, Mylan alleges that one of TMC's production batches of Bivalirudin—Lot No. 1344985—manufactured by Ben Venue Laboratories ("Ben Venue") violated a requirement of the patents-in-suit in that it contained a high level of the impurity Asp9. (*Id.* at 3.) The patents-in-suit claim the New Process produces Bivalirudin with a maximum Asp9 impurity level of 0.6% Asp9, but Mylan alleges that Lot No. 1344985, manufactured using the New Process, produced an Asp9 impurity level of [REDACTED] higher than the maximum level recited in the patent claims. (*Id.* at 2–3; R. 199, Defs.' Reply at 5.) Mylan contends that TMC never disclosed the results of Lot No. 1344985 to the PTO. This failure serves as the basis for Mylan's inequitable conduct claim.

The Court presumes familiarity with the additional background of this litigation, and incorporates herein by reference the background information set forth in the Court's opinion dated August 6, 2012. (R. 119.)

## **II. Current Discovery Dispute**

In August 2012 Mylan subpoenaed the deposition of Dr. Sandra Kuzmich, the attorney at Frommer who prosecuted the patents-in-suit before the PTO. Mylan allegedly had difficulty scheduling Dr. Kuzmich's deposition, finally deposing her on January 3, 2013—eight days before the close of the extended fact discovery period.

During her deposition Dr. Kuzmich testified about a conversation she had had with Dr. Rajashwar Motheram, a TMC scientist. Based on Dr. Kuzmich's testimony, Mylan alleges that

after the issue fee for the patents-in-suit had been paid, but before the patents issued, Dr. Kuzmich received a spreadsheet (“the Spreadsheet”) alerting her to Lot No. 1344985’s irregular results. (Def.’s Reply at 4.) Mylan contends that in determining whether to report these results to the PTO, Dr. Kuzmich spoke with Dr. Motheram, who informed her that “the ‘improved’ process had not been followed” on Lot 1344985. (*Id.*) According to Mylan, based on this conversation Dr. Kuzmich decided that Lot No. 1344985 was immaterial to patentability and that TMC was not obliged to disclose it to the PTO. (*Id.*)

### LEGAL STANDARD

The federal discovery rules liberally assist in preparation for trial and settlement of disputes. *See Bond v. Uteras*, 585 F.3d 1061, 1075 (7th Cir. 2009); *see also Kodish v. Oakbrook Terrace Fire Prot. Dist.*, 235 F.R.D. 447, 450 (N.D. Ill. 2006) (“the scope of discovery should be broad in order to aid in the search for truth”). Federal Rule of Civil Procedure 26(b)(1) provides that “[p]arties may obtain discovery regarding any nonprivileged matter that is relevant to any party’s claim or defense . . . Relevant information need not be admissible at the trial if the discovery appears reasonably calculated to lead to the discovery of admissible evidence.” Fed. R. Civ. P. 26(b)(1). “The burden rests upon the objecting party to show why a particular discovery request is improper.” *Kodish*, 235 F.R.D. at 450. The Seventh Circuit instructs that in a motion to compel “a district court may grant or deny the motion in whole or in part, and similar to ruling on a request for a protective order under Rule 26(c), the district court may fashion a ruling appropriate for the circumstances of the case.” *Gile v. United Air Lines, Inc.*, 95 F.3d 492, 496 (7th Cir. 1996). As with all discovery matters, courts have broad discretion in determining motions to compel. *See James v. Hyatt Regency Chi.*, \_\_\_F.3d\_\_\_, 2013 WL 514097, at \*7 (7th Cir. Feb. 13, 2013); *Peals v. Terre Haute Police Dep’t*, 535 F.2d 621, 629 (7th Cir. 2008).

## ANALYSIS

Mylan contends that during the January 3, 2013, deposition, Dr. Kuzmich waived the attorney-client privilege—either through waiver by disclosure or implied waiver—with regard to Lot No. 1344985 and all communications between Frommer and Dr. Motheram. In response TMC argues that: (1) the conversation between Dr. Kuzmich and Dr. Motheram is not privileged; (2) even if the conversation was privileged, Dr. Kuzmich’s January 3, 2013, testimony did not waive the privilege; and (3) if waiver did occur, the Court should narrowly construe the scope of the waiver. TMC does not directly address Mylan’s argument of implied waiver. Given that TMC has opposed waiver in general, however, the Court will not consider the argument waived and will address the merits of Mylan’s implied waiver argument.<sup>1</sup>

### I. Choice of Law

Before addressing the waiver issue, however, the Court must first determine whether to apply Federal Circuit law or Seventh Circuit law. This case involves claims under the federal patent laws, and consequently the federal common law of privilege governs. *See* Fed. R. Evid. 501; *United States v. Zolin*, 491 U.S. 554, 562 (1989) (“Questions of privilege that arise in the course of the adjudication of federal rights are governed by the principles of the common law . . .”) (internal quotations omitted). In patent cases regional circuit law governs non-patent issues, while Federal Circuit law governs issues of substantive patent law. *In re Spalding Sports Worldwide, Inc.*, 203 F.3d 800, 803 (Fed. Cir. 2000). Federal Circuit law may also govern any substantive or procedural issues “intimately involved in the substance of enforcement of the patent right.” *Flex-Foot, Inc. v. CRP, Inc.*, 238 F.3d 1362, 1365 (Fed. Cir. 2001). Regional circuit law, however, applies to procedural questions not themselves issues of substantive patent

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<sup>1</sup> The Court addresses the scope of waiver by disclosure and implied waiver separately, as the theories could result in a different scope of the waiver.

law unless they (1) pertain to patent law, (2) bear an essential relationship to matters committed by statute to the exclusive control of the Federal Circuit, or (3) clearly implicate the responsibilities of the Federal Circuit in a field within its exclusive jurisdiction. *GFI, Inc. v. Franklin Corp.*, 265 F.3d 1268 (Fed. Cir. 2001).

The present discovery dispute is governed in part by Seventh Circuit law and in part by Federal Circuit law. Mylan's claim of inequitable conduct—the defense underlying the discovery dispute—implicates substantive patent law. *See In re Spalding*, 203 F.3d at 803-04 (recognizing inequitable conduct as an issue of substantive patent law). Furthermore, the discoverability of evidence required to establish and defend against inequitable conduct similarly implicates substantive patent law. *See In re EchoStar Commc'ns Corp.*, 448 F.3d at 1298 (“Federal Circuit law applies when deciding whether particular written or other materials are discoverable in a patent case, if those materials relate to an issue of substantive patent law.”); *see also In re MSTG, Inc.*, 675 F.3d 1337, 1341 (Fed. Cir.), *reh'g denied* (Fed. Cir. 2012) (applying Federal Circuit law to determine whether privilege applies to information related to patent royalties). Therefore, the procedural issue of whether and to what extent waiver applies to privileged information used to establish or defend against a claim of inequitable conduct necessarily implicates substantive patent law, and thus Federal Circuit law, not Seventh Circuit law, governs. *See In re Seagate Tech., LLC*, 497 F.3d 1360, 1367-68 (Fed. Cir. 2007) (finding that the issue of scope of waiver accompanying advice of counsel defense to willful infringement involved substantive patent law, and consequently applying Federal Circuit law).<sup>2</sup> The issue of

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<sup>2</sup> The Federal Circuit has not yet ruled on choice of law regarding privilege and waiver of privilege in the context of inequitable conduct, though several district courts have. *See Martin Marietta Materials, Inc. v. Bedford Reinforced Plastics, Inc.*, 227 F.R.D. 382, 391-92 (W.D. Pa. 2005) (finding that waiver by invocation of advice of counsel defense in the context of justifying failure to disclose prior art to the PTO involved substantive patent law, and applying Federal

waiver by disclosure, however, belongs to the category of “procedural questions that are not themselves substantive patent law issues,” and the Court will apply Seventh Circuit Law to the issue of whether waiver by disclosure has occurred, and the scope of any waiver by disclosure that occurred. *GFI*, 265 F.3d at 1272.<sup>3</sup>

## **II. Waiver by Disclosure**

### **A. Whether The Attorney-Client Privilege Applies**

The attorney-client privilege protects communication between an attorney and her client, *Upjohn Co. v. United States*, 449 U.S. 383, 389 (1981), and extends to communications between an inventor and a patent attorney. *See In re Spalding*, 203 F.3d at 806. It does not matter whether a communication “contain[s] technical information” or “refer[s] to prior art,” as long as the “overall tenor of the document indicates that it is a request for legal advice or services.” *Id.* Moreover, an explicit request for legal assistance is not necessary when such a request is implied. *Id.*

Mylan argues that the attorney-client privilege applies to the underlying communications between Dr. Kuzmich and Dr. Motheram. It argues that Dr. Kuzmich “saw the spreadsheet disclosing the [REDACTED] Asp9 lot . . . spoke with TMC employee Dr. Motheram about the problem lot and . . . determined that the lot was immaterial.” (Memo. Mot. to Compel at 12.) Mylan contends that this is a “classic attorney-client privileged communication concerning a key

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Circuit law); *Info-Hold, Inc., v. Trusonic, Inc.*, No. 1:06CV543, 2008 WL 2949399 at \*2 (S.D. Ohio July 30, 2008) (“[T]he defense of inequitable conduct before the Patent Office is an issue that bears an essential relationship to substantive patent law, [and] Federal Circuit law, not Sixth Circuit law, applies.”). *Cf. Chimie v. PPG Indus., Inc.*, 218 F.R.D. 416, 419 n.4 (D. Del. 2003) (“The better reasoned approach [to choice of law in waiver by reliance on advice of counsel] recognizes that questions of waiver are not unique to patent law and are a matter of either state law . . . or precedent from the regional circuits.”).

<sup>3</sup> Ultimately, Seventh Circuit law and Federal Circuit law treat privilege similarly, and thus the choice of law analysis does not alter the outcome in this case.

strategic decision in prosecution of the patent applications.” (*Id.*) The Court agrees.

Upon receiving the Spreadsheet, Dr. Kuzmich considered disclosing it the PTO, explaining that she wanted “to make sure that anything that was material to patentability was disclosed to the PTO.” (R.189-3, Greb Mot. Decl. Ex. 5 at 194.) Dr. Kuzmich subsequently communicated with Dr. Motheram, who told her that the “batch did not follow the new process.” (*Id.* at 186.) After speaking with Dr. Motheram and several other individuals, Dr. Kuzmich and others concluded that “the process was not followed and therefore this was not part of the new compounding process and therefore it wasn’t material to patentability.” (*Id.* at 195-96.)

The purpose of Dr. Kuzmich’s conversation with Dr. Motheram was to assess patentability and to determine whether TMC had to disclose the batch information to the PTO. These concepts are inherently legal, and the conversation is therefore privileged. *See In re Spalding*, 203 F.3d at 806 (“[S]ince Spalding’s invention record was prepared and submitted primarily for the purposes of obtaining legal advice on patentability . . . we conclude that it is privileged in its entirety.”); *see also Judson Atkinson Candies, Inc. v. Latini-Hohberger Dhimantec*, 529 F.3d 371, 388 (7th Cir. 2008) (quoting *United States v. Defazio*, 899 F.2d 626, 635 (7th Cir. 1990) (“Communications from attorney to client are privileged only if they constitute legal advice, or tend directly or indirectly to reveal the substance of a client confidence.”)).

TMC claims that the phone conversation between Dr. Kuzmich and Dr. Motheram is not privileged because it was not “made for the purpose of seeking or obtaining legal advice;” rather, “Dr. Motheram only provided Dr. Kuzmich information concerning facts.” (Pl.’s Resp. at 5.) TMC further contends that the “transmittal of technical information . . . does not transform that communication into a request for legal advice.” (*Id.* at 6.)

TMC is correct—technical information does not make the document privileged. The



inclusion of technical information also does not, however, “render the document discoverable, because requests for legal advice on patentability or for legal services in preparing a patent application necessarily require evaluation of technical information such as prior art.” *In re Spalding*, 203 F.3d at 806. The fact that the conversation between Dr. Kuzmich and Dr. Motheram involved technical information is not determinative. The “central inquiry is whether the communication is one that was made by a client to an attorney<sup>4</sup> for the purpose of obtaining legal advice or services.” *Id.* The issue of patentability is decidedly legal in nature, and the communication was therefore privileged. *See Bergman v. Aluminum Lock Shingle Corp. of Am.*, 251 F.2d 801, 803 (9th Cir. 1957) (“[T]he question of validity of a patent is a question of law.”)

#### **B. Waiver by Disclosure**

The next question is whether TMC waived the attorney-client privilege when Dr. Kuzmich disclosed the contents of the privileged conversation during her deposition. Waiver by the disclosure of privileged materials is not bound up in substantive patent law, and as such the Court applies Seventh Circuit law. *See GFI*, 265 F.3d at 1272 (finding that regional law applies to waiver by the disclosure of privileged material). A party may waive privilege by knowingly disclosing privileged communications to a third party. *Appleton Papers, Inc. v. E.P.A.*, 702 F.3d 1018, 1025 (7th Cir. 2012). If disclosure occurs, the Court must then determine whether the disclosure was inadvertent. *Judson Atkinson Candies*, 529 F.3d at 388. The Court assesses inadvertence not by a bright line rule but rather by “look[ing] at the circumstances surrounding the disclosure.” *Id.* (citing *Harmony Gold U.S.A., Inc. v. FASA Corp.*, 169 F.R.D. 113, 116

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<sup>4</sup> Though *Spalding* frames the inquiry as whether the communication was “made by a client to an attorney,” the attorney-client privilege applies with equal force to inquiries from an attorney to a client. *See Upjohn*, 449 U.S. at 390 (finding privilege “exists to protect not only the giving of professional advice to those who can act on it, but also the giving of information to the lawyer to enable him to give sound and informed advice”).

(N.D. Ill. 1996). In assessing the circumstances the Court considers “(1) the reasonableness of the precautions taken to prevent disclosure; (2) the time taken to rectify the error; (3) the scope of the discovery; (4) the extent of the disclosure; and (5) the overriding issue of fairness.” *Id.* (citing *Harmony Gold U.S.A.*, 169 F.R.D. at 116-17).

Mylan argues that Dr. Kuzmich’s deposition testimony about her conversation with Dr. Motheram waives attorney-client privilege. Specifically, Dr. Kuzmich testified, in relevant part:

Q: The batch with the Asp9 level of [REDACTED] percent, is it your opinion that that didn’t follow the new process?

A: No, it is not my opinion. It is what I was told.

Q: Who told you that?

A: Dr. Motheram.

Q: Dr. Motheram is a Medicines Company employee?

A: Yes.

Q: Would he have told you that electronically?

A: No.

Q: You had a conversation with him?

A: Yes.

...

Q: You testified earlier that Dr. Motheram told you that the lot we have been talking about with the [REDACTED] percent Asp9 Bivalirudin level, he told you that the new compounding process wasn’t followed; is that right?

A: Yes.

...

Q: I thought you testified he told you that the new compounding process wasn’t followed?

A: Correct, it was his view and I guess The Medicines Company view that the process wasn't followed and that it was under investigation. So that is the information I had.

Q: So he told you two things. One, that the lot was under investigation and, two, that the process wasn't followed?

A: Yes.

(Greb Mot. Decl. Ex. 5 at 186:22–187:12, 190:24–191:6, 191:15–192:2.)

During her deposition, Dr. Kuzmich knowingly disclosed her communication with Dr. Motheram to Mylan. Testimony by TMC counsel further demonstrates that the waiver was not inadvertent. Indeed, TMC's counsel was aware of and even consented to the disclosure. *Cf. Judson Atkinson Candies*, 529 F.3d at 388 (finding inadvertence where attorney produced over 25,000 pages of discovery in which one privileged memo slipped through). The relevant testimony provides:

Q: Did Dr. Motheram tell you why he thought that the lot with the [REDACTED] percent Asp9 bivalirudin level didn't follow the new process?

TMC Counsel: I object based on privilege. Attorney-client. Instruct the witness not to answer.

Mylan Counsel: It is waived.

TMC Counsel: What?

Mylan Counsel: It is waived.

TMC Counsel: What is waived?

Mylan Counsel: You are asserting a privilege around this communication. She is giving an answer. It is waived.

TMC Counsel: Let's take a break for a second.

(*Id.* at 188-89.)

The parties returned after a three minute recess and continued:

TMC Counsel: I am not sure I agree with your characterization about waiver but *to the*

*extent you want to examine what Raj said I am going to permit that.*

...

Q: You testified earlier that Dr. Motheram told you that the lot we have been talking about with the [REDACTED] Asp9 bivalirudin level, he told you that the new compounding process wasn't followed; is that right?

A: Yes.

(*Id.* at 188-89, 190-91) (emphasis added.)

TMC's counsel was aware of the disclosure of the communication between Dr. Kuzmich and Dr. Motheram and allowed it to go forward. As such, the disclosure was not inadvertent and constitutes a waiver of privilege.

### **C. Scope of Waiver by Disclosure**

The Court next turns to the scope of the waiver. Disclosure may result in a complete subject matter waiver, or may result only in a waiver limited to the communication itself. *See Appleton Papers*, 702 F.3d at 1025 (“Generally, a party that voluntarily discloses part of a conversation covered by the attorney-client privilege waives the privilege as to the portion disclosed and to all other communications relating to the same subject matter.”); *Fort James Corp. v. Solo Cup Co.*, 412 F.3d 1340, 1349 (Fed. Cir. 2005) (applying Seventh Circuit law and citing *In re Cont'l Ill. Secs. Litig.*, 732 F.2d 1302, 1314 n.18 (7th Cir. 1984) (“The widely applied standard for determining the scope of a waiver of attorney-client privilege is that the waiver applies to all other communications relating to the same subject matter.”)); *see also Westinghouse Elec. Corp. v. Republic of Philippines*, 951 F.2d 1414, 1423 n.7 (3rd Cir. 1991) (“Partial waiver permits a client who has disclosed a portion of privileged communications to continue asserting the privilege as to the remaining portions of the same communications.”). The Court determines the scope of a waiver based on fairness and consideration of the risk that “a

limited disclosure of privileged communications, if permitted, might result in a party's use of privileged communications supporting its position and simultaneous concealment of communications that do not." *Fort James Corp.*, 412 F.3d at 1349. Whether a party disclosed information in order to gain a tactical advantage in litigation may inform a fairness determination. *See In re von Bulow*, 828 F.2d 94, 101 (2d Cir. 1987) (finding that disclosures made in book authored by attorney did not constitute subject matter waivers because they were not made to gain a tactical advantage in litigation).

TMC's disclosure constitutes a complete subject matter waiver on the subject of Lot No. 1344985. In this case the scope of the waiver extends beyond the actual conversation disclosed in Dr. Kuzmich's deposition -- fairness dictates this broad scope. TMC's waiver of privilege over Dr. Kuzmich's conversation with Dr. Motheram eight days before the close of the extended fact discovery period afforded TMC a tactical advantage in litigation. TMC disclosed Dr. Kuzmich's conversation with Dr. Motheram because it supports its position—namely, it supports the position that Lot No. 1344985 was not procured using the New Process and is therefore not material to patentability—but simultaneously seeks to conceal information that potentially does not support its position. Further discovery on Lot No. 1344985 is needed to settle the materiality of the lot. Indeed, the contention that TMC relied on a single statement by Dr. Motheram in deciding not to disclose Lot No. 1344985, far from settling the matter, raises a host of questions. On what basis did Dr. Motheram ground his belief that the New Process was not followed?<sup>5</sup> Was the phone conversation with Dr. Motheram Dr. Kuzmich's only justification for declining to disclose the lot? Did Dr. Kuzmich make the final determination of whether to disclose the lot to

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<sup>5</sup> Dr. Motheram's alleged contention to Dr. Kuzmich that the New Process was not followed in procuring Lot No. 1344985 is particularly questionable in light of Ben Venue's Quality Investigation Report of Lot No. 1344985, discussed further below in the context of implied waiver.

the PTO, and if not, who else was involved and on what basis did they decide not to disclose?

These are questions to which Mylan is entitled answers in order to properly defend itself in this case.

TMC's assertion that Ben Venue did not follow the New Process with regard to Lot No. 1344985 might be correct. TMC may not, however, buttress this assertion with a sliver of privileged communication while shielding the rest from discovery. Mylan should be able to inquire into the presence of any documents or communications that may shed light on the failure to disclose Lot No. 1344985. As a result of its waiver by disclosure TMC must produce: (1) privileged and non-privileged documents and items in TMC's possession mentioning, discussing, listing, or otherwise relating to Angiomax® Lot No. 1344985; and (2) privileged and non-privileged documents mentioning, reflecting, or relating to communications between Frommer attorneys or employees and TMC mentioning, discussing, listing, or otherwise relating to Angiomax® Lot No. 1344985.<sup>6</sup>

#### **D. Implied Waiver**

In addition to waiver by disclosure, Mylan argues for an implied waiver based on TMC's use of Dr. Motheram's opinion about Lot No. 1344985's materiality to rebut Mylan's inequitable conduct defense. A party may waive attorney-client privilege by putting a privileged communication at issue in the litigation, generally as a defense to a claim. *See Wi-LAN, Inc. v. Kilpatrick Townsend & Stockton LLP*, 684 F.3d 1364, 1370 (Fed. Cir. 2012) ("The doctrine of implied waiver is invoked when a party makes the content of his attorney's advice relevant to

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<sup>6</sup> Contrary to Mylan's argument the subject matter of the waiver does not extend to "all documents on [TMC's] privilege log comprising communications involving Dr. Rajeshhwar Motheram and a Frommer employee," (Def.'s Reply at 14,) but instead only to those relating to Lot No. 1344985. This production is not limited to communications involving just Dr. Motheram and Frommer employees -- it extends to communications relating to Lot No. 1344985 between *any* TMC scientist or employee and any Frommer employee or attorney.

some claim or defense in the case.”).

Inequitable conduct is a matter of substantive patent law, and the issue of waiver in this case is so bound up in the matter of inequitable conduct that it too is a matter of substantive patent law. *See In re MSTG, Inc.*, 675 F.3d 1337, 1341 (Fed. Cir. 2012); *In re EchoStar Commc’ns Corp.*, 448 F.3d at 1298 (“Federal Circuit law applies when deciding whether particular written or other materials are discoverable in a patent case, if those materials relate to an issue of substantive patent law.”); *Flex-Foot*, 238 F.3d at 1365 (finding that Federal Circuit law applies to any substantive or procedural issues “intimately involved in the substance of enforcement of the patent right.”). Federal Circuit law therefore governs the issue of implied waiver in this case.

Inequitable conduct consists of an intentional breach of the duty of candor in dealings with the PTO. *GFI*, 265 F.3d at 1273. *See also Avid Identification Sys., Inc. v. Crystal Import Corp.*, 603 F.3d 967, 974 (Fed. Cir. 2010). Inequitable conduct in prosecuting a patent can render the patent unenforceable. *Therasense, Inc. v. Becton, Dickinson & Co.*, 649 F.3d 1276, 1288 (Fed. Cir. 2011) (“the remedy for inequitable conduct is the ‘atomic bond’ of patent law”). A finding of inequitable conduct requires a showing that (1) the applicant failed to disclose material information to the patent office, and (2) that she did so with the specific intent to deceive the PTO. *Id.* at 1290. Generally, “the materiality required to establish inequitable conduct is but-for materiality.” *Id.* The Federal Circuit has elaborated:

When an applicant fails to disclose prior art to the PTO, that prior art is but-for material if the PTO would not have allowed a claim had it been aware of the undisclosed prior art. Hence, in assessing the materiality of a withheld reference, the court must determine whether the PTO would have allowed the claim if it had been aware of the undisclosed reference. In making this patentability determination, the court should apply the preponderance of the evidence standard and give claims their broadest

reasonable construction.

*Id.* at 1291-92 (citations omitted).

Mylan argues that in defending against its inequitable conduct defense, “Ms. Kuzmich has put her good faith into issue by asserting in deposition that she decided not to disclose Lot 1344985 to the Patent Office based on the content of her alleged communications with Dr. Motheram.” (Defs.’ Reply at 13.) Mylan further contends that in putting her state of mind at issue, TMC has “waived privilege with respect to any other privileged information concerning Lot 1344985,” and that “[f]airness requires that TMC produce the privileged documents that Mylan needs to challenge Ms. Kuzmich’s assertions of good faith.” (*Id.*) The Court agrees.

In her deposition, Dr. Kuzmich raised her conversation with Dr. Motheram as a basis for determining that Ben Venue did not follow the New Process in making Lot No. 1344985, and that it was therefore not material to patentability of the patents-in-suit. (R. 189, Mot. Decl. Ex. 5 at 186-87.) If the New Process *was* followed, a reasonable examiner would likely find Lot No. 1344985, which had an Asp9 level [REDACTED] greater than the limit in the claims, to be important and material to patentability. Thus, whether the New Process was followed is vital to the materiality prong of Mylan’s inequitable conduct defense. *See Afro-Lecon, Inc. v. United States*, 820 F.2d 1198, 1204-05 (Fed. Cir 1987) (A party waives a communication through implied waiver if it “places the matter subject to the privilege in issue and the information is vital to the defendant’s case.”). TMC has waived privilege through its reliance on Dr. Motheram’s assertion that the New Process was not followed in Lot No. 1344985 to shield it from Mylan’s inequitable conduct defense. *In re EchoStar Commc’ns Corp*, 448 F.3d at 1299 (“Once a party announces that it will



rely on advice of counsel . . . the attorney-client privilege is waived.”).<sup>7</sup>

The “widely applied standard for determining the scope of a waiver of attorney-client privilege is that the waiver applies to all other communications relating to the same subject matter.” *Fort James Corp.*, 412 F.3d at 1349; *see also In re Seagate*, 497 F.3d at 1370 (“[A]sserting the advice of counsel defense waives . . . attorney-client privilege for all communications on the same subject matter, as well as any documents memorializing attorney-client communications.”). Waiver is broad in scope, extending “beyond the document initially produced out of concern for fairness, so that a party is prevented from disclosing communications that support its position while simultaneously concealing communications that do not.” *Fort James Corp.*, 412 F.3d at 1349 (citing *Weil v. Inv./Indicators, Research & Mgmt., Inc.*, 647 F.2d 18, 24 (9th Cir. 1981); *see also In re Keeper of Records*, 348 F.3d 16, 23 (1st Cir. 2003) (“It is well accepted that waivers by implication can sometimes extend beyond the matter actually revealed.”). While there is no bright line test for determining the extent of a waiver, courts should “weigh the circumstances of the disclosure, the nature of the legal advice sought and the prejudice to the parties of permitting or prohibiting further disclosure.” *Fort James Corp.*, 412 F.3d at 1349-50; *see also In re Keeper of Records*, 348 F.3d at 23 (determining that evaluation of implied waiver demands a “fastidious sifting of the facts”).

The issue squarely at the center of TMC’s defense against Mylan’s inequitable conduct claim is whether Lot No. 1344985 was material to patentability, and whether TMC had a duty to

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<sup>7</sup> The court in *Martin Marietta Materials* faced a similar argument to Mylan’s and found an implied waiver. 227 F.R.D. at 398-97 (finding that an attorney’s deposition testimony that she “recommended that no new disclosure was necessary based on . . . communications [with outside counsel] . . . clearly put in issue Plaintiff’s attorneys’ understanding of its applicable duty to disclose with regard to material prior art and the role which attorney-client communications and advice of counsel played in the decision not to disclose certain prior art, such that the Plaintiff has waived the attorney-client privilege with regard to such communications about the disclosure of material prior art to the United States Patent and Trademark Office”).

disclose it to the PTO. Dr. Kuzmich has placed at issue in this litigation TMC's understanding of its duty to disclose Lot No. 1344985 and the process by which it came to decide not to disclose Lot No. 1344985. TMC counters Mylan's inequitable conduct defense by claiming that the New Process was not followed and Lot No. 1344985 is therefore not material, but absent more information it is by no means clear that the New Process was not followed in creating Lot No. 1344985. In Ben Venue's Quality Investigation Report of Lot No. 1344985, for example, it notes that "[REDACTED]"

[REDACTED]) Indeed, the only indication in the record that Lot No. 1344985's high Asp9 value was due to Ben Venue's failure to follow the New Process is Dr. Kuzmich's testimony that Dr. Motheram told her it was not followed.<sup>8</sup> (Greb Mot. Decl. Ex. 5 at 187.)

In light of Ben Venue's Quality Investigation Report of Lot No. 1344985 indicating no error on its part, any decision—by Dr. Kuzmich, Dr. Motheram, or others—that Ben Venue failed to follow the New Process and that the lot was therefore not material to patentability was likely based on other conversations or documents. Mylan is entitled to examine whether such conversations or documents exist. The scope of the waiver extends to all documents relating to Lot No. 1344985, as it is not clear that the Spreadsheet was the only document relied on in deciding not to disclose. Further, the scope of the waiver extends to communications related to Lot No. 1344985 between all individuals at Frommer and all individuals at TMC, as it is

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<sup>8</sup> TMC argues that Dr. Fred Musso's testimony provides further support that the New Process was not followed. (Def.'s Reply at 11.) The Court is not persuaded. [REDACTED]

[REDACTED] It does not conclusively demonstrate that "Lot No. 1344985 was not made using the 'new process.'" (Def.'s Reply at 11.)

similarly not clear that Dr. Kuzmich and Dr. Motheram were the only individuals involved with the decision nor that either had final authority to make the decision not to disclose the lot to the PTO. *See In re Pioneer Hi-Bred Int'l, Inc.*, 238 F.3d 1370, 1374-75 (Fed. Cir. 2001) (finding that reliance on advice of counsel “waived the attorney-client privilege with respect to all documents which formed the basis for the advice, all documents considered by counsel in rendering that advice, and all reasonably contemporaneous documents reflecting discussions by counsel or others concerning that advice”).

The scope of the implied waiver is thus the same as the scope of the waiver by express disclosure of Dr. Kuzmich’s conversation with Dr. Motheram during Dr. Kuzmich’s deposition. It extends to the subject matter of Lot No. 1344985, which includes: (1) privileged and non-privileged documents and items in TMC’s possession mentioning, discussing, listing, or otherwise relating to Angiomax® Lot No. 1344985; and (2) privileged and non-privileged documents mentioning, reflecting, or relating to communications between attorneys or employees of Frommer Lawrence & Haug law firm (“Frommer”) and The Medicine Company mentioning, discussing, listing, or otherwise relating to Angiomax® Lot No. 1344985.

### **CONCLUSION**

For the foregoing reasons the Court grants in part and denies in part the remaining aspects of Mylan’s motion to compel. TMC must produce the following documents to Mylan by March 29, 2013:

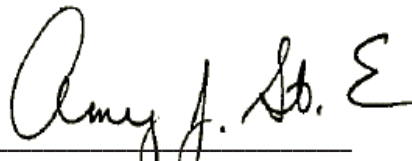
- (1) Privileged and non-privileged documents and items in TMC’s possession mentioning, discussing, listing, or otherwise relating to Angiomax® Lot No. 1344985; and
- (2) Privileged and non-privileged documents mentioning, reflecting, or relating to communications between attorneys or employees of Frommer Lawrence & Haug law firm (“Frommer”) and The Medicine Company mentioning, discussing, listing, or otherwise relating to Angiomax® Lot No. 1344985.

As noted at the last status hearing, the Court also grants Mylan's motion to compel Dr. Motheram for further deposition. TMC must also produce Dr. Motheram for a four hour deposition to be conducted on or before April 9, 2013. The Court denies Mylan's motion to compel all documents comprising communications involving Dr. Motheram and a Frommer employee to the extent they do not relate to Angiomax® Lot No. 1344985.

Additionally, to the extent TMC has "no documents discussing Lot No. 1344985" in its possession, (Defs.' Reply at 10,) TMC's General Counsel must provide a sworn affidavit that all privileged and non-privileged documents and items in TMC's possession mentioning, discussing, listing, or otherwise relating to Angiomax® Lot No. 1344985 or to communications between attorneys or employees of Frommer Lawrence & Haug law firm ("Frommer") and The Medicine Company mentioning, discussing, listing, or otherwise relating to Angiomax® Lot No. 1344985 have been collected and produced. TMC must file this affidavit with the Court by April 2, 2013.

**Date:** March 19, 2013

**ENTERED**

A handwritten signature in black ink, appearing to read "Amy J. St. E", written over a horizontal line.

**AMY J. ST. EVE**

**United States District Court Judge**